

DEC 17 2004

VIII. Summary of Safety and Effectiveness

SUBMITTER: VERTEBRON Inc.
400 Long Beach Blvd.
Stratford, CT 06615

CONTACT PERSON: Luis Nesprido

DATE PREPARED: November 11, 2004

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis

COMMON NAME: Cervical Plating System

PROPRIETARY NAME: VERTEBRON SCP™ Cervical Plate System

PREDICATE DEVICES: VERTEBRON SCP™ Cervical Plate System – K040003

INTENDED USE: The VERTEBRON SCP™ Cervical Plate System is intended for non pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients. The VERTEBRON SCP™ Cervical Plate System is intended for non cervical pedicle fixation for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

MATERIALS: The material used is medical grade titanium material that conforms to ASTM F136.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Mr. Luis Nesprido
Vertebron, Inc.
400 Long Beach Boulevard
Stratford, Connecticut 06615

Re: K043181
Trade/Device Name: Vertebron SCP™ Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: November 15, 2004
Received: November 17, 2004

Dear Mr. Nesprido:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

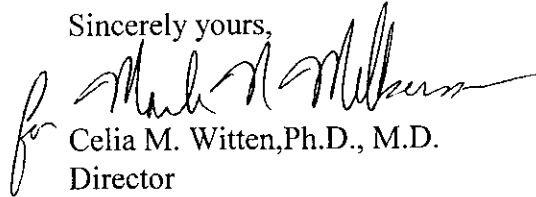
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Luis Nesprido

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Indications for Use

510(k) Number (if known): K043181

Device Name: VERTEBRON SCP™ Cervical Plate System

Indications For Use:

The VERTEBRON SCP™ Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions. The SCP™ Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7 levels.

Prescription Use: X
(Per 21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use: _____
(21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark H. Millerson

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K043181